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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,387	01/21/2004	Christopher Pearce	009.4002	4868

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EXAMINER

GREENE, DANA D

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/762,387

Applicant(s)

PEARCE ET AL.

Examiner

Dana D. Greene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/21/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 3 is objected to because of the following informalities: "an user" should be replaced with "a user". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Independent claims 1, 22, 40, 62 and dependent claims 2-8, 11-20, 23, 25-39, 41-48, 54-60, 63, 64, 66, 67, 69-74, and 75-78 stand rejected under 35 U.S.C. §102(e) as being anticipated by Bardy (US 6,827,690 B2, hereinafter "Bardy"). Bardy is considered to disclose:

an ECG monitor and data collector configured to receive electrocardial data about the patient's heart (see col. 2, ln. 48-54, Bardy). The disclosed patient monitoring device is considered to anticipate the claimed ECG monitor and data collector because both monitor and collect data regarding the electrocardiogram of the patient's heart in the form of hardware/software that permits the coupling of the apparatus to the body of the patient;

a cardiac marker data collector configured to receive electrocardial data about the patient's heart (see col. 2, ln. 12-20, Bardy). The disclosed cardiac enzyme release-storing device is considered to anticipate the claimed cardiac marker data collector because both are capable of documenting the presence and levels of serum enzymes, which may facilitate confirmation of myocardial infarction;

a data processing and recording module in electrical communication with said ECG monitor and data collector and said cardiac marker data collector and configured to record said electrocardial data and said cardiac marker data (see col. 6, ln. 12-37 and col. 7, ln. 65 – col. 8, ln. 5, Bardy). The disclosed device is considered to anticipate the claimed data processing and recording module because both process and store electrocardial data to facilitate identification and/or treatment.

With reference to claims 2, 4-6, 41, 42, and 65, Bardy is considered to disclose: the apparatus for documenting the myocardial ischemia of a patient's heart of claim 1, said data processing and recording module comprising at least one of a processor and a memory device (see col. 6, ln. 63 – col. 7, ln. 7, Bardy). The disclosed central processing unit and RAM are considered to anticipate the claimed processing and memory module because both configurations are capable of processing data received from the ECG monitor and storing digital data provided to the processor.

Referring to claims 3, 43-45, and 63 Bardy is considered to teach: the apparatus further comprising a user interface configured to permit entry of said cardiac marker data for receipt by said cardiac marker data collector (see col. 3, ln. 20-60, Bardy). The disclosed system and method for diagnosing is considered to

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anticipate the claimed user interface because both are used to interpret data to indicate to a physician or user that myocardial ischemia of the heart of a patient may be present.

With reference to claims 7-8, Bardy is considered to disclose:

the apparatus comprising a display module in electrical communication with said data processing and recording module and configured to display at least one of said electrocardial data and said cardiac marker data and wherein the data processing and recording module is configured to suggest a treatment for myocardial ischemia (see col. 6, ln. 63 – col. 7, ln. 10 and col. 11, ln. 64 – col. 12, ln. 5, Bardy).

Referring to claims 11-13, 16, 25, 36-37, 50-53, 69-71, and 74, Bardy is considered to disclose:

data processing and recording module configured to detect a change over time of said electrocardial data and wherein said cardiac marker data collector is configured to identify a time and a date of receipt of said cardiac marker data (see col. 10, ln. 20-36, Bardy).

With reference to claims 14-15, 29, 33, 54-56, and 72-73 Bardy is considered to disclose:

data processing and recording module configured to generate a prompt to a user of the apparatus to perform a cardiac marker test (see col. 3, ln. 20-60, Bardy).

Referring to claims 17-18, 38-39, 57-58, and 75-76, Bardy is considered to disclose:

The apparatus further comprising a patient data collector that is in electrical communication with said data processing and recording module and is configured to

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receive patient data comprising at least one of a name of the patient, an identification number of the patient, an age of the patient, a sex of the patient, and race of the patient (see col. 11, ln. 7-37, Bardy).

With reference to claims 19-20, 26-28, 59-60, and 77-78 Bardy is considered to disclose:

The apparatus further comprising at least one patient parameter monitor and collector that is in electrical communication with said data processing and recording module and that is configured to receive data regarding a physiological state of the patient (see col. 6, ln. 38-50, Bardy). The disclosed server system is considered to anticipate the claimed data processing and recording module because both measure sets of analyzed a physiological measure indicative of myocardial ischemia.

With reference to claim 22, Bardy is considered to disclose:

obtaining electrocardial data about the patient's heart; receiving results of a cardiac marker test performed on the patient (see col. 3, ln. 20-45, Bardy). The disclosed method of measuring the patient's cardiovascular information is considered to anticipate the claimed method of obtaining electrocardial data because both techniques monitor and collect data regarding the electrocardiogram of a patient's heart and monitor the results of a cardiac marker test;

storing said electrocardial data and said results of said cardiac marker test in a patient report; and displaying said patient report (see col. 3, ln. 20-45, Bardy). The disclosed technique is considered to anticipate the claimed method because store data

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and display the logged changes for comparison to indicator thresholds to detect the principal cardiovascular data.

Referring to claim 23, Bardy is considered to disclose:

The method for documenting the myocardial ischemia of a patient's heart, the step of displaying said patient report comprising displaying said patient report on a visual display (see col. 6, ln. 25-38, Bardy). The disclosed monitor is considered to anticipate the claimed display because both display patient information for the patient and physician.

With reference to claims 30-32, 34-35, 64, and 66-67, Bardy is considered to teach:

the method further comprising the step of analyzing said electrocardial data to determine if myocardial ischemia is suggested by said electrocardial data (see col. 2, ln. 24-38, Bardy). The disclosed method of analysis is considered to teach the claimed step because both collect and study data pertaining to the myocardial ischemia and study courses of action and treatment that should be taken.

Referring to claims 40 and 46-48, Bardy is considered to teach:

means for receiving electrocardial data about the patient's heart (see col. 3, ln. 20-45, Bardy). The disclosed means of recording patient cardiovascular information is considered to anticipate the claimed means for receiving electrocardial data because both measure a patient's cardiovascular information via an external or implantable medical device;

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means for receiving cardiac marker data about the patient's heart (see col. 3, ln. 20-45, Bardy). The disclosed technique is considered to anticipate the claimed means because both receive serum creatinine kinase, increased serum troponin, increased ventricular end diastolic pressure, and reduced cardiac output for indication of myocardial infarction;

means for processing said electrocardial data and said cardiac marker data (see col. 13, ln. 25-33, Bardy). The disclosed method of using the patient query engine is considered to anticipate the claimed means for processing the electrocardial data because both techniques are focused on processing patient physiological information such as electrocardial data;

means for recording said electrocardial data and said cardiac marker data into a patient record (see col. 3, ln. 20-60, Bardy). The disclosed means for logging the patient cardiovascular information is considered to anticipate the claimed means for recording said electrocardial data because both collect and record a patient's cardiovascular and electrocardial information, and the presences of proteins and enzymes that appear in abnormally elevated levels as a result of cardiac tissue injury;

means for displaying said patient record (see col. 3, ln. 20-60, Bardy). The disclosed means of logging changes is considered to anticipate the claimed display means because both produce patient data in a form capable of being modified and examined.

With reference to claim 62, Bardy is considered to disclose:

a cardiac marker data collector configured to receive cardiac marker data about the patient's heart (see col. 3, ln. 20-60, Bardy). The disclosed database is considered to anticipate the claimed cardiac marker data collector because both hold information relating to the proteins and enzymes that appear in abnormally elevated levels as a result of cardiac tissue injury;

a data processor in electrical communication with said cardiac marker data collector (see col. 6, ln. 12-37 and col. 7, ln. 65 – col. 8, ln. 5, Bardy). The disclosed device is considered to anticipate the claimed data processing and recording module because both process and store electrocardial data to facilitate identification and/or treatment;

a memory module in electrical communication with said data processor and configured to record said electro cardiogram waveform and said cardiac marker data (see col. 9, ln. 40-65, Bardy). The disclosed database module is considered to anticipate the claimed memory module because both function as a storage medium capable of maintaining digital data and instructions for recording cardiograms and cardiac marker data;

a display module in electrical communication with said processor and configured to display at least one of the electrocardiogram waveform and said cardiac marker data (see col. 6, ln. 63- col. 7, ln. 7, Bardy). The disclosed display is considered to anticipate the claimed display module because both are capable of displaying the processor's interpretation of the data to the user of the apparatus or any other physician.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 24, 49, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy. Bardy is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed printer. It would have been an obvious matter of design choice to use the teachings of Bardy with a printer for the purpose of communicating electrocardial signals and physiological data to the patient or physician.

Claim 10 is rejected under 35 U.S.C. §103(a) as being unpatentable over Bardy in view of Nataragan et al. (US 6, 501,983 B1, hereinafter "Nataragan"). Bardy is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed algorithm module. However, Nataragan is considered to teach the claimed algorithm module (see col. 2, ln. 12-16 and col. 11, ln. 1-5, Nataragan). It would have been obvious to one of ordinary skill in the art to combine the teachings of Bardy with the algorithm of Nataragan for the purpose of documenting the myocardial ischemia of a patient's heart.

Claims 21, 61, and 79 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bardy. Bardy is considered to disclose the claimed invention as discussed above under the anticipatory rejection, except for the claimed housing. It would have been obvious to one having ordinary skill in the art at the time the invention

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was made to incorporate a housing for protection for the modules and ECG monitor since it was known in the art that these devices work best in conjunction with protective coverings.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dana D. Greene



George Manuel
Primary Examiner